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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/528,034	03/17/2000	Kevin C. Carter	RTI-1181A	4253

7590

03/03/2003

Donald J. Pochopien  
MCANDREWS, HELDS, & MALLOY, LTD.  
CITICORP CENTER, 34TH FLOOR  
500 WEST MADISON STREET  
CHICAGO, IL 60661

EXAMINER

STEWART, ALVIN J

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 03/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

NK.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/528,034		CARTER ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Alvin J Stewart		3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 December 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,4,5,14,17 and 19-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 14 and 17 is/are allowed.
- 6) ☒ Claim(s) 1 and 19-24 is/are rejected.
- 7) ☒ Claim(s) 2, 4, and 5 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 March 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                    | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                           | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2,5</u> . | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Request for Continued Examination***

The request filed on December 16, 2002 for a Request for Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/528,034 is acceptable and a RCE has been established. An action on the RCE follows.

### ***Specification***

The disclosure is objected to because of the following informalities: at the beginning of the specification the Applicant has to enter the Continuing Data of US Patent 6,497,726 and in the detailed description of the drawings the Applicant has not describe Figures 2A, 2B, 2C and delete the description of Figure 2.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 19, the word "naturally" renders the claim indefinite because the meaning of the word is not well understood. What does the word "naturally" means? The Examiner suggests changing the word "naturally" by any other word that may have support on the specification. Correction is required.

*Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Simon et al US Patent 5,951,560.

Stone et al discloses a bone tendon bone graft (10) comprising a tendon (30) and a bone block (12) having a first end (self tapping portion) and a second end (16) (see Fig. 1). The first and second ends are tapered (see Fig. 1).

Claims 19, 20 and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by McGuire US Patent 5,562,669.

McGuire discloses a bone-tendon-bone graft comprising a first bone block (25) and second bone block (25) interconnected by a tendon (20), wherein the two blocks have been pre-shaped into a dowel (see Figs. 1 and 5). Additionally, the dowel has radius cuts (see Fig. 4a, element 50).

Claims 19 and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Simon et al US Patent 5,951,560.

Simon et al discloses a bone-tendon-bone graft (see Fig. 35) comprising a first bone block (49B) and second bone block (53B) interconnected by a tendon (51B), wherein the two blocks have been pre-shaped into a dowel (see Fig 35). Additionally, the dowel has a tapered region (see Fig. 35).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simon et al US Patent 5,951,560 in view of Kurland US Patent 4,400,833.

Simon et al discloses the invention substantially as claimed. However, Simon et al does not disclose the use of xenograft tissue and a process to minimize the level of antigenic agents.

Kurland teaches the use of xenograft tissue surrounded by a mesh of synthetic fabric. The xenograft tissue is inserted within the human body for the purpose of substituting human tissue (see col. 1, lines 6-15). Additionally, Kurland discloses the use of glutaraldehyde to make stable and minimize the level of antigenic agents of heterologous tissue in humans (see col. 1, lines 38-44).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the autograft tissue of the Simon et al reference with the xenograft tissue of the Kurland reference in order to increase the availability of replacement grafts (no matter if is from another species) when need it. It is well known in the art the lack of compatible tissue replacement when need it, therefore it would have been obvious to one having ordinary skill in the art to use a xenograft tissue in order to replace a patients ligament.

***Allowable Subject Matter***

Claims 14 and 17 are allowed.

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Claims 2, 4 and 5 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

*Response to Arguments*

Claims 3, 6-13, 15 and 16 and 18 have been canceled in previous amendments.

Regarding claim 1, the phrase "unitary" has been interpreted the same as the phrase "integral". The term integral was held not to be limited to a fabrication of the parts from a single piece of material, but was inclusive of other means of maintaining the parts fixed together as a single unit. In re Larson et al., 340 F 2d 965, 144 U.S.P.Q. 347 (C.C.P.A. 1965). "Integral" is sufficiently broad to embrace constructions united by such means as fastening and welding. In re Hotte, 475 F 2d 644, 177 U.S. P.Q. 326 (C.C.P.A. 1973). For the above reasons, the Examiner maintains the same rejection. In order to overcome the rejection the Applicant has to add limitations regarding the tendon, as described in claim 2 and/or positively claim the second bone block. The claims disclosed above are given their broadest reasonable interpretation. In re Pearson, 181 USPQ 641 (CCPA 1974). For the above reasons, the suture element (30) of the Stone et al reference has been interpreted as the "tendon".

Regarding claims 2, 4 and 5, after a careful examination of the Applicant's remarks in papers #13 and #17 the Examiner has withdrawn the 35 U.S.C. 103(a) rejection made in the previous Office Action and has object only to the above claims (see above).

Regarding the new claims 19-24, the Examiner has found prior art in order to reject them (see above).

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*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J Stewart whose telephone number is 703-305-0277. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-308-2708 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



Alvin Stewart  
February 26, 2003